Applicant: James A. Laugharn, Jr. et al. Attorney's Docket No.: 07985-012002

Serial No.: 09/530,478 Filed: April 28, 2000

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## **REMARKS**

Claims 72-72, 75-80, 82-84, 91-92, and 98-99 are under examination. Claims 72, 91, and 98 have been amended. Support for these amendments can be found throughout the application, for example on page 31, lines 16-18. No new matter has been added. Please consider the following remarks.

Claims 72-73, 79-80, 82, 91-92, and 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Frantz et al. U.S. Patent 5,536,496 (Frantz) and Chen et al. U.S. Patent 5,104,674 (Chen).

All of the claims relate to a method of releasing molecules from cells by exposure to an elevated, <u>isostatic</u> pressure of at least 500 psi in a pressure chamber to form lysed cells, whereupon the molecules are released from the lysed cells within the pressure chamber. The claimed invention is distinct from the French style press disclosed in both Frantz and Chen. As noted in the Office Action, Frantz discloses lysing cells by <u>continuous passage through the pressure chamber</u> of the homogenizer, which creates an <u>immediate pressure drop</u> as the sample passes through the chamber. (See Office Action, p. 5, first full paragraph.) Chen discloses a method of microfragmenting complexes by subjecting a suspension or slurry to <u>intense shear</u>. The intense shear occurs when the material is being passed through the homogenation element. The suspension or slurry (e.g. a dispersion of a polysacharide or peptide) may be <u>passed through</u> a cell disruptor or other high shear zone a sufficient number of times to provide a desired particle size. (See Office Action, paragraph bridging pp. 5-6.)

The present invention requires isostatic pressure that releases cellular molecules within a pressure chamber. The isostatic pressure provides uniform pressure on the material with little to no shear force generated. This gentle process helps to preserve the integrity of biomolecules (e.g., proteins and nucleic acids) during the process. On the other hand, the French style press described by both Frantz and Chen does not teach the use of isostatic pressure as required by the present invention, but rather relates to the application of pressure to a material from one angle (e.g., from the top), which physically forces the material to move through an orifice (e.g., a homogenizer as described in Chen). The pressure applied in the French style press creates a high rate of shear in the material and a rapid change in pressure as the material is being pushed

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through the orifice. Accordingly, neither Frantz nor Chen teach the use of isostatic pressure recited in the present invention.

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Moreover, one of skill in the art would not be motivated, upon the reading of Frantz and Chen, to modify the French type press to include the limitations of the present invention. Rather, Frantz and Chen both teach away from the present invention with the specific use of shearing force to release cellular contents. Accordingly, one of skill in the art, reading Frantz and Chen, would be not motivated to modify the disclosures to use the isostatic pressure recited in the present invention, which results in little to no shearing forces.

In view of the foregoing, Applicants assert that no *prima facie* case of obviousness has been established and request that the rejection be withdrawn.